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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,774	08/21/2003	Ichiro Yamashita	59516-36pp-15876.009.	6930
20277	7590	03/23/2006	EXAMINER	
MCDERMOTT WILL & EMERY LLP			MOHAMED, ABDEL A	
600 13TH STREET, N.W.			ART UNIT	
WASHINGTON, DC 20005-3096			PAPER NUMBER	

1654

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,774	<b>Applicant(s)</b> YAMASHITA, ICHIRO	
	<b>Examiner</b> Abdel A. Mohamed	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 20-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/21/03, 11/23/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **ACKNOWLEDGMENT FOR PRIORITY, PRELIMINARY AMENDMENT, IDS, STATUS OF THE APPLICATION AND CLAIMS**

1. This application is filed on 08/21/03 as a Continuation of Application No. PCT/JP02/10127 having a filing date of 09/27/02, which claims priority of Japanese Application No. 2001-305273, filed 10/01/01. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. The preliminary amendment filed 02/13/04 and the Information Disclosure Statement (IDS) and Form PTO-1449 filed 08/21/03 and 11/23/04, respectively are acknowledged, entered and considered. In view of Applicant's request claim 1 has been amended, claims 2-19 have been canceled and claims 20-26 have been added. Claims 1 and 20-26 are now pending in the application.

#### **OBJECTION TO THE BRIEF DESCRIPTION OF THE DRAWINGS IN THE DISCLOSURE**

2. The disclosure is objected to of the following informalities: Figure 7 and Figure 8 have multiple figures. The figures should be amended on page 6 in the instant specification to read Figures 7A and 7B and Figures 8A-8E with the description of each of the figures, respectively. Appropriate correction to the specification is required.

### **ILLUSTRATION OF PRIOR ART**

3. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### **CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite in the recitation "is performed at a temperature of not less that 80<sup>0</sup> C and not more than 100<sup>0</sup> C". The recitation of the term "that" is believed to be typographical error. Appropriate correction is required.

### **CLAIMS REJECTION-35 U.S.C. 112<sup>1st</sup> PARAGRAPH.**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are no teachings in the specification to show the enablement of using a thermophile apoferritin protein and performing the step b) claimed at a temperature of not less than 80<sup>0</sup> C and not more than 100<sup>0</sup> C. The specification teaches the use of apoferritin as a protein for introducing cobalt. Although, the instant specification states that other proteins such as Dps protein or CCMV protein (mesophilic proteins), which can hold metal particles therein may be used instead of apoferritin (See page 16, lines 19-21 in the instant specification). However, a thermophile apoferritin protein was not known at the time the instant invention was filed. It was only known on 2005 when the reference of Matias et al (Acta Cryst. Vol. F67, pp. 503-506, 2005) published. Matias et al report the crystallization and preliminary structure analysis of *PfFtn*, the ferritin from *Pyrococcus furiosus*. *P. furiosus* is a marine strictly anaerobic fermentative hyperthermophilic archaeon with optimal growth temperature of 373 K (See e.g., page 503, last paragraph). On page 504, left column, first paragraph the reference states that the high thermostability of *PfFtn* will probably be explained from structural data.

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The mechanism of iron incorporation into ferritins is under debate. In the hyperthermophilic *PfFtn*, presteady-state kinetics of iron uptake can be slowed drastically at ambient temperatures, which may allow following of the iron-incorporation pathway in protein crystals. Claim 25 claims the use of a thermophile apoferritin at a temperature between 80<sup>0</sup> C and 100<sup>0</sup> C, which was not known at the time of filing the instant specification. Thus, the specification does not enable any person skilled in the art to which it pertains, or which is most nearly connected, to use the invention commensurate in scope with the claim. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention.

#### **CLAIMS REJECTION-35 U.S.C. § 103(a)**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al (Inorg. Chem., Vol. 39, pp. 1828-1830, 2000) taken with Yang et al (Biochem. J., Vol. 338, pp. 615-618, 1999).

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The primary reference of Douglas et al discloses a method for producing a cobalt-protein complex wherein the protein is apoferritin by preparing a solution including  $\text{Co}^{2+}$  ions, adjusting the solution to pH 8.5 unbuffered (overlaps with the claimed ranges of 8.0 to 8.8) and thereby adding an oxidizing agent such as  $\text{H}_2\text{O}_2$  to said solution to withstand temperature up to  $70^\circ\text{C}$ . The reference also teaches that cobalt can be accumulated as a cobalt oxyhydroxide ( $\text{CoO}(\text{OH})$ ) core with assistance of  $\text{H}_2\text{O}_2$  oxidation (See e.g., Introduction, Results and Discussion, Conclusion and Figures 1-3) as directed to claims 1, 22-24 and 26.

Although, the primary reference clearly teaches the production of cobalt-apoferritin complex containing cobalt particles as admittedly acknowledged on page 4, lines 4-5 in the instant specification and as shown above. However, the primary reference of Douglas et al differs from claims 1 and 20-26 in not teaching the use of a buffer solution such as HEPES for adjusting the pH and the use of thermophile apoferritin with a temperature of  $80^\circ\text{C}$  to  $100^\circ\text{C}$ . Nevertheless, the secondary reference of Yang et al teaches the use of Tris and Good's buffer including HEPES for emphasizing the importance of using proper experimental conditions when investigating the iron oxidation properties of ferritin (See e.g., Introduction). Further, the secondary reference shows on Figures 1 and 4, page 616, left column, and under effects of buffers on  $\text{Fe}(\text{II})$  autoxidation that buffers demonstrate  $\text{Fe}(\text{II})$  oxidation kinetics in the presence or absence of ferritin compared with pH stat solutions wherein the HEPES buffer itself inhibits oxidation as disclosed on Figure 1, trace C. Hence, the reference of Yang et al clearly teaches that buffers catalyze the autooxidation. Thus, it is within the ordinary

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skill of the art to which this invention pertains to employ buffers such as HEPES (design of choice), which are widely known to the art and widely employed in general (preferred) as admitted on page 15, lines 20 to page 16, lines 18 in the instant specification for adjusting the pH. Therefore, the teachings of the secondary reference of Yang et al of the use of a buffer such as HEPES for adjusting the pH, are known or suggested in the art, as seen in the secondary reference, and including such features (i.e., buffers such as HEPES) into the method for producing a cobalt-apoferritin complex containing cobalt particles of the primary reference, would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof for the intended purpose of producing cobalt-protein complex.

With respect to the use of thermophile apoferritin with a temperature of 80<sup>0</sup> C to 100<sup>0</sup> C as claimed in claim 25; it is known in the art as acknowledged on page 11, lines 12-22 in the instant specification that normally the reaction solution is reacted at room temperature and the temperature of the reaction solution may be increased from 40<sup>0</sup> C to 70<sup>0</sup> C to facilitate the reaction (See also the primary reference on page 1828, left column, paragraph 2 for using up to 70<sup>0</sup> C). The specification further states on page 11, lines 19-22 that as another option, if thermophile apoferritin is used, the temperature may be increased to about 80<sup>0</sup> C to 100<sup>0</sup> C for the intended purpose of improving the crystallinity of generated CoO(OH). However, use of thermophile apoferritin was not known at the time the instantly invention was filed for the reasons discussed above. The primary reference teaches the production of cobalt-apoferritin by employing temperature not greater than 70<sup>0</sup> C as discussed above, however, if a thermophile



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apoferritin is used, it would have been obvious for one of ordinary skill in the art to increase the temperature accordingly because of the nature of the protein (i.e., a thermophile apoferritin). Thus, in view of the above, if a thermophile apoferritin is used, one of ordinary skill in the art would have been motivated to perform at temperature higher than 70<sup>0</sup> C, and as such, the selection and/or optimization of the appropriate temperature for a thermophile apoferritin is within the skill of the art to which this invention pertains.

Therefore, in view of the above, the combined teachings of the prior art clearly makes *prima facie* obvious a method for producing a cobalt-protein complex such as cobalt-apoferritin and/or thermophile apoferritin complex comprising the steps of preparing a solution including Co<sup>2+</sup> ions, a protein, and HEPES buffer solution having a pH of 8-8.8 and adding an oxidizing agent such as H<sub>2</sub>O<sub>2</sub> and thereby making the protein contain particles composed of cobalt and performed at the claimed temperatures, absent of sufficient objective factual evidence or unexpected results to the contrary.

### CONCLUSION AND FUTURE CORRESPONDANCE

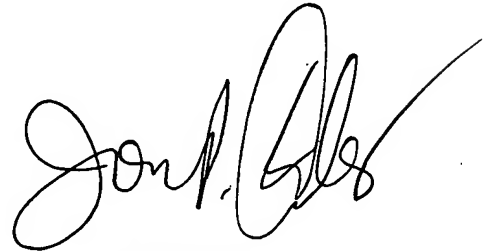
7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**

 Mohamed/AAM  
March 13, 2006